12/24/0



PATENT Attorney Docket No. 030229

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Benjamin V. Treadwell

Group Art Unit No.:

Serial No.: 10/678,371

METHODS OF ATTENUATING AUTOIMMUNE DISEASE AND

COMPOSITIONS USEFUL

THEREFOR

Filing Date: October 3, 2003

INFORMATION DISCLOSURE STATEMENT

Pittsburgh, Pennsylvania 15222

December 23, 2003

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicant, in accordance with his duty of disclosure pursuant to 37 C.F.R. § 1.56, hereby advises the United States Patent and Trademark Office of the references listed on the accompanying form PTO/SB/08A (substitute for 1449A/PTO) *Information Disclosure Statement by Applicant*. A copy of each of the non-patent literature documents is herewith enclosed.

"Express Mail" mailing label number <u>EU990164282US</u>

Date of Deposit <u>December 23</u>, 2003

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, Alexandria, VA 22313-1450

PI-1099301 v1

Applicant notes that although the cited references may be relevant to the examination of the above-referenced application, under 37 C.F.R. § 1.97(h), the filing of this *Information Disclosure Statement* "shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b)."

Respectfully submitted,

Jesse A. Hirshman Registration No. 40,016

Attorney for Applicant

KIRKPATRICK & LOCKHART LLP Henry W. Oliver Building 535 Smithfield Street Pittsburgh, Pennsylvania 15222-2312

Telephone: (412) 355-8966 Facsimile: (412) 355-6501 E-mail: jhirshman@kl.com U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Superitute for form 1449A/PTO

STATEMENT BY APPLICANT

(use as many sheets as necessary)

3

Sheet

Complete if Known

Application Number 10/678,371

Filing Date October 3, 2003

First Named Inventor Benjamin V. Treadwell

Group Art Unit

Examiner Name

Attorney Docket Number 030229

	Document Number Publication Date Name of Patentee or Applicant of Cited Document Pages, Columns, Lines, Where Rele							
Examiner Initials *	No.1	Number - Kind Code ² (if known)	MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear			
		US- 3,031,376	4/24/1962	Levin et al.				
		US- 3,863,633	2/4/1975	Ryde et al.				
	1	US- 4,623,667	11/18/1986	Gans et al.				
		US- 4,670,471	6/2/1987	Clark				
		US- 4,874,794	10/17/1989	Katz				
	i -	US- 5,071,879	12/10/1991	Katz				
	Ì	US- 5,135,956	8/4/1992	Borg et al.				
	<u> </u>	US- 5,166,219	11/24/1992	Katz				
	i	US- 5,194,451	3/16/1993	Katz				
		US- 5,534,554	7/9/1996	Katz et al.				
		US- 5,663,156	9/2/1997	Granja et al.				
***************************************	_	US- 5,843,919	12/1/1998	Burger				
		US- 5,856,316	1/5/1999	Granja et al.				
		US- 5,952,393	9/14/1999	Sorkin, Jr.				
		US- 6,121,319	9/19/2000	Somers				
	 	US- 6,136,795	10/24/2000	Florio				
		US- 6,197,832	3/6/2001	Sorkin, Jr.				
		US- 6,225,354	5/1/2001	Perez				
-		US- 6,245,811	6/12/2001	Horrobin et al.				
		US- 2001/0006656A1	7/5/2001	Harlan et al.				
		US- 6,303,139	10/16/2001	Passi et al.				
	1	US- 2001/0034338A1	10/25/2001	Sorkin, Jr.				

	FOREIGN PATENT DOCUMENTS					
		Foreign Patent Document		Name of Patentee or	Pages, Columns, Lines, Where Relevant	
Examiner Initials*	Cite No.1	Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Passages or Relevant Figures Appear	T ⁶
····						

Examiner Signature	Date Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional) . ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Supprinte for form 1449A/PTO

THE TRADE

INFORMATION DISCLOSURE EMENT BY APPLICANT

Complet if Known Application Number 10/678,371 October 3, 2003 Filing Date Benjamin V. Treadwell First Named Inventor **Group Art Unit Examiner Name** 030229

(use as many sheets as necessary)

Attorney Docket Number Sheet

	U.S. PATENT DOCUMENTS					
Examiner	Cite No.1	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevar Passages or Relevant Figures Appear	
Initials *	NO.	Number - Kind Code ² (if known)				
		US- 2001/0034364A1	10/25/2001	Gasper et al.		
		US- 6,313,179	11/6/2001	Pope et al.		
		US- 6,355,274	3/12/2002	Dartey et al.		
		US- 2002/0077361A1	6/20/2002	Peet et al.		
		US- 2002/0077317A1	6/20/2002	Das		
		US- 2002/0099099A1	7/25/2002	Gamble et al.		
		US- 6,436,431	8/20/2002	Hoffpauer et al.		
		US- 2002/0132035A1	9/19/2002	Tamarkin et al.		
		US- 2002/0156122A1	10/24/2002	Mach		
		US- 2002/0159973A1	10/31/2002	Mach		
		US- 2002/0159974A1	10/31/2002	Mach		
		US- 2002/0161026A1	10/31/2002	Paralkar		
		US- 6,525,083	2/25/2003	Acton, III et al.		
		US- 2003/0054978A1	3/20/2003	Babish		
		US- 6,537,980	3/25/2003	Hansen		
		US- 2003/0060488A1	3/27/2003	Sugiyama et al.		
	1	US- 2003/0060500A1	3/27/2003	Mach		
		US- 2003/0060501A1	3/27/2003	Mach		
		US- 2003/0060502A1	3/27/2003	Mach		
		US- 2003/0065019A1	4/3/2003	Mach		
		US- 6,548,715	4/15/2003	Bouillon et al.		
		US- 6,559,174	5/6/2003	Lin et al.		
	1	US- 2003/0096876A1	5/22/2003	Gamble et al.		
	1	US- 6,569,461	5/27/2003	Tillyer et al.		
		US- 6,573,255	6/3/2003	Bretting		
	1	US- 6,613,920	9/2/2003	Steinmeyer et al.		

		FOREIGN PA	TENT DOCU	MENTS		
		Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines, Where Relevant	
Examiner Initials*	Cite No. ¹	Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Date	Applicant of Cited Document	Passages or Relevant Figures Appear	T ⁶

	and the second s	
Examiner Signature	Date Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional) . ² See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

ubstitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known **Application Number** 10/678,371 October 3, 2003 Filing Date Benjamin V. Treadwell First Named Inventor **Group Art Unit Examiner Name**

(use as many sheets as necessary)

of 3 Attorney Docket Number 030229 Sheet-

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Τ²
-		Garcion, E., et al., Treatment of experimental autoimmune encephalomyelitis in rat by 1,25-dihyroxyvitamin D3 leads to early effects within central nervous system, Acta Neuropathol, 105:438-448, Jan. 2003.	
		Greenwood, J., et al., Lovastatin inhibits brain endothelial cell Rho-mediated lymphocyte migration and attenuates experimental autoimmune encephalomyelitis, FASEB J. 17(8):905-7, published online March 5, 2003.	
		Mariani, S. M., Silencing Autoimmunity in Multiple Sclerosis, Lupus, and Rheumatoid Arthritis, Highlights From the 90 th Meeting of the American Association of Immunologists, May 6-10, 2003, Medscape Molecular Medicine 5(1), 2003.	
		Wekerle, H., Tackling multiple sclerosis, Nature, 420:39-40, Nov. 7, 2002.	
		Youssef, S., et al., The HMG-CoA reductase inhibitor, atorvastatin, promotes a Th2 bias and reverses paralysis in central nervous system autoimmune disease, Nature, 420:78-84, Nov. 7, 2002.	
		Zittermann, A., Review article, Vitamin D in preventive medicine: are we ignoring the evidence?, British Journal of Nutrition, 89:552-572, May 2003.	

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.